UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

PFIZER INC.,

Civil Action No. 2:17-cv-4180 (JCJ)

Plaintiff,

VS.

JOHNSON & JOHNSON and JANSSEN BIOTECH, INC.,

Defendants.

JOHNSON & JOHNSON AND JANSSEN BIOTECH INC.'S ANSWER TO PLAINTIFF'S COMPLAINT

Defendants Johnson & Johnson and Janssen Biotech, Inc. (collectively, the "J&J Defendants") answer Plaintiff Pfizer Inc.'s Complaint (the "Complaint") as follows:

- 1. The J&J Defendants deny that they have undertaken efforts to suppress competition or deprive society of the benefits of competition in any way. The J&J Defendants deny the third sentence of Paragraph 1 insofar as it contains material in quotation marks the source of which is not identified. The J&J Defendants deny the remaining allegations in Paragraph 1.
- 2. The J&J Defendants admit that rheumatoid arthritis, plaque psoriasis, and Crohn's disease are conditions that can be treated with infusion therapy through infliximab. The J&J Defendants admit these conditions may be chronic and require long-term treatment. The J&J Defendants deny the remaining allegations in Paragraph 2.

- 3. The J&J Defendants admit that they have owned patents relating to Remicade. The J&J Defendants admit that Remicade was the only infliximab product on the market from 1998 until Inflectra launched in 2016 and that it generated approximately \$4.8 billion in U.S. sales in 2016. The J&J Defendants deny that they employed improper exclusionary tactics at any point. Except as expressly admitted, the J&J Defendants deny the remaining allegations in Paragraph 3.
- 4. The J&J Defendants admit that Inflectra received marketing approval under the Biologics Price Competition and Innovation Act ("BPCIA"). The remaining allegations of Paragraph 4 state legal conclusions as to the purpose of the BPCIA to which no response is required; to the extent a response is required, the J&J Defendants respectfully refer the Court to the BPCIA for its contents and deny the remaining allegations in Paragraph 4.
 - 5. The J&J Defendants admit the allegations in Paragraph 5.
- 6. The J&J Defendants admit that they have publicly identified a "Biosimilar Readiness Plan." Except as expressly admitted, the J&J Defendants deny the remaining allegations in Paragraph 6.
 - 7. The J&J Defendants deny the allegations in Paragraph 7.
- 8. The J&J Defendants admit that they enter into contracts with certain insurers that relate to formulary placement and rebates and that in some cases those contracts include provisions giving a preferred status to Remicade over a biosimilar infliximab. Except as expressly admitted, the J&J Defendants deny the allegations in Paragraph 8.
- 9. The J&J Defendants admit that there are patients across the country who are benefitting extensively from their use of Remicade. The J&J Defendants are without knowledge or information sufficient to form a belief as to the truth of whether insurers have made it clear to

Pfizer that its net cost for Inflectra would need to be low enough to offset the loss of J&J rebates and therefore deny those allegations. Except as expressly admitted, the J&J Defendants deny the remaining allegations in Paragraph 9, except respectfully refer the Court to the Johnson & Johnson, Q3 2016 Results Earnings Call Transcript cited in Paragraph 9 for its contents. The J&J Defendants further state that the date of the Q3 2016 Results Earnings Call was October 18, 2016 and not October 14, 2016, as alleged in Paragraph 9.

- 10. The J&J Defendants deny that J&J has caused widespread gaps in Inflectra's insurance coverage and further deny that 70 percent of commercially insured patients have been foreclosed by J&J's insurer contracts. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegation that 90 percent of healthcare provider accounts using infliximab had purchased no Inflectra at all and therefore deny that allegation. The J&J Defendants deny the remaining allegations in Paragraph 10.
 - 11. The J&J Defendants deny the allegations contained in Paragraph 11.
 - 12. The J&J Defendants deny the allegations contained in Paragraph 12.
- 13. The J&J Defendants admit that for a time after Inflectra's launch, Remicade's WAC and ASP increased, and that as of October 2017, Remicade's ASP was at least 10% higher than Inflectra's ASP. Except as expressly admitted, the J&J Defendants deny the remaining allegations in Paragraph 13.
- 14. The J&J Defendants respectfully refer the Court to the Q2 2017 Results Earnings Call Transcript cited in Paragraph 14 for its contents. The J&J Defendants deny the remaining allegations in Paragraph 14.
 - 15. The J&J Defendants deny the allegations in Paragraph 15.

- 16. The first sentence of Paragraph 16 states a legal conclusion to which no response is required; to the extent a response is required, the J&J Defendants deny the first sentence of Paragraph 16. The J&J Defendants deny the remaining allegations in Paragraph 16.
- 17. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 17 and therefore deny those allegations.
- 18. The J&J Defendants admit that Pfizer is a corporation organized and existing under the laws of Delaware and that Pfizer's principal place of business in the United States is located at 235 East 42nd Street, New York, New York 10017. The J&J Defendants further admit that Pfizer is "a research-based international pharmaceutical company which researches, develops, manufactures, and sells pharmaceutical products across the spectrum, from branded innovator products to generics and over-the-counter medications." The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 18 and therefore deny those allegations.
 - 19. The J&J Defendants admit the allegations in Paragraph 19.
- 20. Defendant Johnson & Johnson admits that it is a corporation organized and existing under the laws of New Jersey with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson admits that it is an international pharmaceutical company and that its subsidiaries have supplied an infliximab marketed as Remicade between 1998 and 2016. The J&J Defendants deny the remaining allegations in Paragraph 20.
 - 21. Defendant Janssen Biotech, Inc. admits the allegations in Paragraph 21.

- 22. The allegations in Paragraph 22 state a legal conclusion to which no response is required; to the extent a response is required, the J&J Defendants deny the allegations in Paragraph 22.
- 23. The allegations in Paragraph 23 state a legal conclusion to which no response is required.
- 24. The allegations in Paragraph 24 state a legal conclusion to which no response is required.
- 25. The allegations in Paragraph 25 state a legal conclusion to which no response is required.
- 26. The allegations in Paragraph 26 state a legal conclusion to which no response is required; to the extent a response is required, the J&J Defendants deny that there has been a violation of law or any injury to the Plaintiff.
- 27. The allegations in Paragraph 27 state a legal conclusion to which no response is required.
- 28. The J&J Defendants admit the allegations in Paragraph 28, except respectfully refer the Court to the FDA website cited in Paragraph 28 for its contents.
- 29. Paragraph 29 states legal conclusions as to the purpose of the Hatch-Waxman Act to which no response is required; to the extent a response is required, the J&J Defendants admit that Congress enacted the Hatch-Waxman Act in 1984. The J&J Defendants otherwise deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 29 and therefore respectfully refer the Court to the text of the Hatch-Waxman Act for its contents and deny the remaining allegations in Paragraph 29.

- 30. The J&J Defendants respectfully refer the Court to the FDA website cited in Paragraph 30 for its contents. The J&J Defendants otherwise deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 30 and therefore deny those allegations.
- 31. Paragraph 31 states legal conclusions as to the purpose of the BPCIA to which no response is required; to the extent a response is required, the J&J Defendants admit that the BPCIA was introduced in 2009 and signed into law in 2010 and respectfully refer the Court to the FDA website cited in Paragraph 31 for its contents.
- 32. Paragraph 32 states legal conclusions as to the purpose of the BPCIA to which no response is required. To the extent Paragraph 32 contains allegations that refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations.
- 33. Paragraph 33 states legal conclusions as to the purpose and contents of the BPCIA to which no response is required; to the extent a response is required, the J&J Defendants respectfully refer the Court to the text of 42 U.S.C. § 262(i)(2) for its contents.
- 34. The J&J Defendants admit that differences exist between biosimilars and Hatch-Waxman generics and are not substitutable with the RLD. The J&J Defendants respectfully refer the Court to the BPCIA and the referenced FDA draft guidelines for their contents and deny the remaining allegations in Paragraph 34.
 - 35. The J&J Defendants admit the allegations in Paragraph 35.
 - 36. The J&J Defendants admit the allegations in Paragraph 36.
 - 37. The J&J Defendants admit the allegations in Paragraph 37.

- 38. The J&J Defendants admit the allegations in Paragraph 38.
- 39. The J&J Defendants deny the allegations in Paragraph 39.
- 40. The J&J Defendants admit that Remicade sales have increased steadily on an annual basis. The J&J Defendants deny that there have been consistent increases in Remicade's ASP and otherwise deny the remaining allegations in Paragraph 40.
- 41. The J&J Defendants admit that Remicade has been a successful product and improved the lives of patients around the world. The J&J Defendants deny the remaining allegations in Paragraph 41.
- 42. The J&J Defendants admit that the FDA approved Inflectra (infliximab-dyyb) on April 5, 2016. To the extent Paragraph 42 contains allegations that refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 42, except respectfully refer the Court to the FDA website cited in Paragraph 42 for its contents.
- 43. The J&J Defendants admit that Janssen Biotech, Inc. filed suit against Pfizer and Celltrion in the United States District Court for the District of Massachusetts and that a judgment was entered on August 17, 2016. The J&J Defendants further admit that the United States Patent and Trademark Office issued a final decision in its examination of the Remicade Patent. The J&J Defendants respectfully refer the Court to the 2016 Bloomberg article for its contents and to the dockets of the referenced cases for their respective contents. The J&J Defendants deny the remaining allegations in Paragraph 43 of the Complaint.

- 44. The J&J Defendants admit that Pfizer began selling Inflectra in November 2016. The J&J Defendants otherwise deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 44 and therefore deny those allegations.
- 45. The J&J Defendants admit that Remicade and Inflectra are approved for the same indications except for pediatric ulcerative colitis, which has been designated as having orphan drug status by the FDA. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 45 and therefore deny those allegations.
- 46. The J&J Defendants admit that Pfizer introduced Inflectra with a list price 15 percent below that of Remicade's WAC. To the extent the allegations in Paragraph 46 refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. Except as expressly admitted, the J&J Defendants deny the remaining allegations in Paragraph 46.
- 47. To the extent the allegations in Paragraph 47 refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 47.
- 48. The J&J Defendants admit that many patients who are prescribed Remicade have some form of insurance coverage or qualify for patient assistance. Except as expressly admitted,

the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 48 and therefore deny those allegations.

- 49. The J&J Defendants admit that Remicade is administered intravenously. The J&J Defendants further admit that in the pharmacy benefit setting, physicians frequently prescribe a drug and the patient procures the medication him or herself at the pharmacy. The J&J Defendants admit that in the pharmacy benefit context, generally neither the prescribing physician nor the institution with which the physician is affiliated bears financial risk with respect to the drug selected, i.e., the drug is not purchased and stocked in advance by providers at their own cost. Except as expressly admitted, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 49 and therefore deny those allegations.
- 50. The J&J Defendants admit that medical benefit products are frequently administered at a clinic or other healthcare provider site, and that generally, the provider itself first purchases the drug product for use in the infusion treatment of patients and then later seeks reimbursement for the drug from a third party payer (a practice commonly referred to as "buy and bill"). The J&J Defendants otherwise deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 50 and therefore deny those allegations.
- 51. The allegations in Paragraph 51 refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, and the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations.

- 52. The J&J Defendants admit that commercial insurers frequently publish medical policies enumerating the drug products they will cover under the medical benefit and the terms under which they will do so. To the extent the allegations in Paragraph 52 refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 52.
- 53. The J&J Defendants admit that providers may purchase infliximab for use with their infusion services. The J&J Defendants deny the remaining allegations in Paragraph 53.
- 54. To the extent the allegations in Paragraph 54 refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 54.
- 55. The J&J Defendants respectfully refer the Court to the Q3 2016 Results Earnings Call Transcript cited in Paragraph 55 for its contents. The J&J Defendants deny the remaining allegations in Paragraph 55.
- 56. The J&J Defendants respectfully refer the Court to the text of the July 20, 2017 and July 25, 2017 Bernstein Research articles for their contents. The conclusions drawn by Pfizer from these articles refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants; the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. The J&J Defendants deny the remaining allegations contained in Paragraph 56.

- 57. The J&J Defendants deny the allegations contained in Paragraph 57.
- 58. The J&J Defendants admit that they enter into contracts with certain insurers that relate to formulary placement and rebates and that in some cases those contracts include provisions giving a preferred status to Remicade over a biosimilar infliximab. The J&J Defendants further respectfully refer the Court to the articles authored by Smolen and Gal cited in Paragraph 58 for their contents. The conclusions drawn by Pfizer from these articles refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants; the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. Except as expressly admitted, the J&J Defendants deny the allegations in Paragraph 58.
- 59. The J&J Defendants admit that they enter into contracts with certain insurers that relate to formulary placement and rebates and that in some cases those contracts include provisions giving a preferred status to Remicade over a biosimilar infliximab. To the extent the allegations in Paragraph 59 refer to the knowledge, conduct or actions of persons other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 59.
- 60. The J&J Defendants admit that exclusive contracts can—in certain circumstances—be perfectly appropriate. To the extent the allegations in Paragraph 60 otherwise refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 60.

- 61. To the extent the allegations in Paragraph 61 refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 61.
- 62. To the extent the allegations in Paragraph 62 refer to the knowledge, conduct, opinions or actions of persons, entities or defendants other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 62.
- 63. To the extent the allegations in Paragraph 63 refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 63.
 - 64. The J&J Defendants deny the allegations in Paragraph 64.
 - 65. The J&J Defendants deny the allegations in Paragraph 65.
- 66. The J&J Defendants respectfully refer the Court to the Hakim and Ross article cited in Paragraph 66 for its contents. The conclusions drawn by Pfizer from this article refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants; the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations.

- 67. The J&J Defendants respectfully refer the Court to the Q3 2016 Results Earnings Call Transcript cited in Paragraph 67 for its contents. The J&J Defendants admit that J&J's portfolio includes Simponi, Simponi Aria, and Stelara. The J&J Defendants further admit that Simponi and Simponi Aria generated for J&J approximately \$1.7 billion in 2016 and Stelara generated for J&J approximately \$3.2 billion in 2016. The J&J Defendants deny the remaining allegations in Paragraph 67.
 - 68. The J&J Defendants deny the allegations in Paragraph 68.
- 69. To the extent the allegations in Paragraph 69 refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations.
- 70. The J&J Defendants deny the allegations contained in Paragraph 70, except respectfully refer the Court to the text of the Bloomberg article cited in Paragraph 70 for its contents. The conclusions drawn by Pfizer from this article refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants; the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations.
- 71. The J&J Defendants deny the allegations contained in Paragraph 71, except respectfully refer the Court to the text of the "Commercial Reimbursement Information" brochure cited in Paragraph 71 for its contents.
- 72. The J&J Defendants deny that J&J has caused widespread gaps in Inflectra's insurance coverage and further deny that 70 percent of commercially insured patients have been

foreclosed by J&J's insurer contracts. The J&J Defendants deny the remaining allegations in Paragraph 72.

- 73. The J&J Defendants deny the allegations in Paragraph 73.
- 74. The J&J Defendants admit that after Inflectra's introduction, J&J began offering certain providers additional rebates and/or discounts on Remicade. The J&J Defendants deny the remaining allegations in Paragraph 74.
- 75. The J&J Defendants admit that certain of their provider contracts allow providers to earn rebates across different drugs sold by the J&J Defendants. The J&J Defendants deny the remaining allegations in Paragraph 75, except respectfully refer the Court to the article authored by Gal cited in Paragraph 75 for its contents. The conclusions drawn by Pfizer from this article refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants; the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations.
- 76. To the extent the allegations in Paragraph 76 refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 76.
- 77. Paragraph 77 states legal conclusions to which no response is required; to the extent a response is required, the J&J Defendants deny the allegations in Paragraph 77.
 - 78. The J&J Defendants deny the allegations in Paragraph 78.
 - 79. The J&J Defendants deny the allegations in Paragraph 79.
 - 80. Paragraph 80 states a legal conclusion to which no response is required.

- 81. The J&J Defendants admit that between 2007 and 2017, Remicade's ASP increased more than 62 percent. The J&J Defendants deny that unit sales of Remicade have grown 15 percent during the period from 2012 to 2016. The J&J Defendants deny the remaining allegations in Paragraph 81.
- 82. The J&J Defendants deny the allegations in Paragraph 82, except respectfully refer the Court to the Q1 2017 Transcript cited in Paragraph 82 for its contents.
- 83. The J&J Defendants deny that rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, Crohn's disease, and plaque psoriasis together constitute the "Relevant Indications." The J&J Defendants otherwise admit the allegations in Paragraph 83.
- 84. Paragraph 84 states legal conclusions as to the relevant product market to which no response is required. To the extent a response is required, the J&J Defendants deny that the "Relevant Indications" are those identified by Plaintiff and further deny the remaining allegations in Paragraph 84.
- 85. The J&J Defendants deny that the "Relevant Indications" are those identified by Plaintiff. The J&J Defendants further deny that the infusion-administered therapies identified in Paragraph 85 constitute the "Relevant Products." The J&J Defendants further state that Stelara IV (ustekinumab) (J&J) (human interleukin-12 and -23 antagonist) is not approved for intravenous-administered therapy for Psoriatic Arthritis or Plaque Psoriasis. The J&J Defendants further deny the remaining allegations in Paragraph 85.
- 86. The J&J Defendants deny that the "Relevant Indications" are those identified by Plaintiff. The J&J Defendants further deny the remaining allegations in Paragraph 86.
- 87. The J&J Defendants admit that the biologic products identified in Paragraph 87 are capable of self-administration in certain instances. The J&J Defendants deny that all infusion

sessions take upwards of two hours and further deny that the "Relevant Indications" are those identified by Plaintiff. To the extent the remaining allegations in Paragraph 87 refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations.

- 88. Paragraph 88 states legal conclusions and conjectures about the future to which no response is required; to the extent a response is required, the J&J Defendants deny the allegations contained in Paragraph 88.
- 89. The J&J Defendants admit that infusion and non-infusion treatments have a different means of administration. Except to the extent specifically admitted in response to Paragraphs 49, 50, and 87 of the Complaint, the J&J Defendants deny the remaining allegations in Paragraph 89.
- 90. To the extent the allegations in Paragraph 90 refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 90.
- 91. The J&J Defendants admit that infusion and non-infusion therapies may be offered at different list price points but deny the remaining allegations in Paragraph 91.
- 92. Paragraph 92 states legal conclusions and conjectures about the future to which no response is required; to the extent a response is required, the J&J Defendants deny the allegations contained in Paragraph 92.

- 93. Paragraph 93 states legal conclusions to which no response is required; to the extent a response is required, the J&J Defendants deny the allegations contained in Paragraph 93.
- 94. Paragraph 94 states legal conclusions to which no response is required; to the extent a response is required the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 94 and therefore deny those allegations. The J&J Defendants further deny that the "Relevant Indications" are those identified by Plaintiff.
- 95. Paragraph 95 states legal conclusions as to product markets to which no response is required; to the extent a response is required, the J&J Defendants admit that non-hospital clinics administer infusion therapies and deny the remaining allegations in Paragraph 95, except respectfully refer the Court to the U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines (2010), § 3 for its contents.
- 96. Paragraph 96 states legal conclusions as to product markets to which no response is required; to the extent a response is required, the J&J Defendants deny that the "Relevant Products" are those identified by Plaintiff and further deny the remaining allegations in Paragraph 96.
- 97. Paragraph 97 states legal conclusions as to product markets to which no response is required. Further, to the extent the allegations in the first sentence of Paragraph 97 are premised on unidentified speculation about what discovery may show, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. To the extent a response is required, the J&J Defendants deny the remaining allegations in Paragraph 97.

- 98. Paragraph 98 states legal conclusions to which no response is required; to the extent a response is required, the J&J Defendants deny the allegations contained in Paragraph 98.
- 99. The J&J Defendants admit that Renflexis, sponsored by Merck and Samsung, has been approved by the FDA. The J&J Defendants deny the remaining allegations in Paragraph 99.
 - 100. The J&J Defendants deny the allegations contained in Paragraph 100.
- 101. Paragraph 101 states legal conclusions to which no response is required; to the extent a response is required, the J&J Defendants deny the allegations contained in Paragraph 101.
 - 102. The J&J Defendants deny the allegations contained in Paragraph 102.
 - 103. The J&J Defendants deny the allegations contained in Paragraph 103.
 - 104. The J&J Defendants deny the allegations contained in Paragraph 104.
 - 105. The J&J Defendants deny the allegations contained in Paragraph 105.
 - 106. The J&J Defendants deny the allegations contained in Paragraph 106.
- 107. Answering Paragraph 107, the J&J Defendants incorporate by reference their responses to Paragraphs 1 through 106.
- 108. The allegations in Paragraph 108 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 108.
- 109. The allegations in Paragraph 109 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 109.

- 110. The allegations in Paragraph 110 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 110.
- 111. The allegations in Paragraph 111 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 111.
- 112. The allegations in Paragraph 112 are legal conclusions to which no response is required; to the extent a response is required, the J&J Defendants admit that the ASP for Remicade increased for a time after Inflectra was launched and deny the remaining allegations in Paragraph 112.
- 113. The allegations in Paragraph 113 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 113.
- 114. The allegations in Paragraph 114 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 114.
- 115. Answering Paragraph 115, the J&J Defendants incorporate by reference their responses to Paragraphs 1 through 114.
- 116. The allegations in Paragraph 116 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 116.

- 117. The allegations in Paragraph 117 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 117.
- 118. The allegations in Paragraph 118 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 118.
- 119. The allegations in Paragraph 119 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 119.
- 120. The allegations in Paragraph 120 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants admit that the ASP for Remicade increased for a time after Inflectra was launched and deny the remaining allegations in Paragraph 120.
- 121. The allegations in Paragraph 121 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 121.
- 122. The allegations in Paragraph 122 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 122.
- 123. Answering Paragraph 123, the J&J Defendants incorporate by reference their responses to Paragraphs 1 through 122.
 - 124. The J&J Defendants deny the allegations in Paragraph 124.
 - 125. The J&J Defendants deny the allegations in Paragraph 125.

- 126. The J&J Defendants admit that they enter into contracts with certain insurers that relate to formulary placement and rebates. To the extent the allegations in Paragraph 126 refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 126.
- 127. To the extent the allegations in Paragraph 127 refer to the knowledge, conduct, opinions, or actions of persons or entities other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of those allegations and therefore deny those allegations. The J&J Defendants deny the remaining allegations in Paragraph 127.
 - 128. The J&J Defendants deny the allegations in Paragraph 128.
 - 129. The J&J Defendants deny the allegations contained in Paragraph 129.
- 130. Paragraph 130 states legal conclusions to which no response is required; to the extent a response is required, the J&J Defendants deny the allegations in Paragraph 130.
- 131. Paragraph 131 states legal conclusions to which no response is required; to the extent a response is required, the J&J Defendants deny the allegations contained in Paragraph 131.
- 132. Paragraph 132 states legal conclusions to which no response is required; to the extent a response is required, the J&J Defendants deny the allegations contained in Paragraph 132 and incorporate by reference their responses to Paragraphs 102 through 106.

- 133. Paragraph 133 states legal conclusions to which no response is required; to the extent a response is required, the J&J Defendants deny the allegations contained in Paragraph 133.
- 134. Answering Paragraph 134, the J&J Defendants incorporate by reference their responses to Paragraphs 1 through 133.
- 135. The allegations in Paragraph 135 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 135.
- 136. The allegations in Paragraph 136 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 136.
- 137. The allegations in Paragraph 137 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 137.
- 138. The J&J Defendants admit that the ASP for Remicade increased for a time after Inflectra was launched. The J&J Defendants deny the remaining allegations in Paragraph 138.
- 139. The allegations in Paragraph 139 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 139.
- 140. The allegations in Paragraph 140 are legal conclusions to which no response is required; to the extent that a response is required, the J&J Defendants deny the allegations in Paragraph 140.

- 141. The J&J Defendants deny that Plaintiff is entitled to relief, including but not limited to the relief sought in sub-parts A-E of the "Prayer for Relief."
 - 142. The J&J Defendants deny that Plaintiff is entitled to a jury trial for any issues.

AFFIRMATIVE DEFENSES

- 1. Plaintiff fails to state a claim against the J&J Defendants upon which relief may be granted.
- 2. Plaintiff's claims are barred by its lack of Article III and antitrust standing to prosecute its claims.
 - 3. Plaintiff has failed to mitigate its damages.
- 4. Plaintiff's claims against the J&J Defendants are barred because the J&J Defendants have complied with all applicable regulations of the federal and state governments.
- 5. Plaintiff's claims for injunctive relief against the J&J Defendants are barred by the doctrines of in pari delicto and/or unclean hands.
- 6. Plaintiff's claims should be dismissed to the extent they are barred by the doctrines of waiver, laches, and estoppel.
- 7. Plaintiff's claims are barred, in whole or in part, because any and all injuries and damages alleged in the Complaint, the fact and extent to which are expressly denied by the J&J Defendants, were directly and proximately caused by or contributed to by the statements, acts, and/or omissions of Plaintiff.
- 8. Plaintiff's claims are barred, in whole or in part, because it would be unjustly enriched if it were allowed to recover any part of the damages alleged in the Complaint.

RESERVATION OF RIGHTS

The J&J Defendants reserve the right to assert additional legal defenses as they become known, including all affirmative defenses that it may have against Plaintiff. Additionally, the J&J Defendants reserve the right to amend this Answer to the extent they are entitled to do so.

Dated: August 24, 2018

By: /s/ Leslie E. John

Leslie E. John (PA Id. No. 62290) Matthew I. Vahey (PA Id. No. 315920) BALLARD SPAHR LLP 1735 Market Street, 51st Floor Philadelphia, PA 19103 Tel: (215) 665-8500 john@ballardspahr.com vaheym@ballardspahr.com

William F. Cavanaugh (admitted *pro hac vice*)

Adeel A. Mangi (admitted *pro hac vice*) Jonathan H. Hatch (admitted *pro hac vice*)

George A LoBiondo (admitted *pro hac vice*)

Sara A. Arrow (admitted *pro hac vice*)
PATTERSON BELKNAP WEBB & TYLER
LLP

1133 Avenue of the Americas New York, NY 10036-6710 Tel: (212) 336-2000 wfcavanaugh@pbwt.com aamangi@pbwt.com jhatch@pbwt.com globiondo@pbwt.com

sarrow@pbwt.com

Thomas O. Barnett (admitted *pro hac vice*)

Ashley E. Bass (admitted *pro hac vice*) COVINGTON & BURLING LLP 850 Tenth Street, NW

Washington, DC 20001-4956

Tel: (202) 662-6000 tbarnett@cov.com

abass@cov.com

Counsel for Johnson & Johnson and Janssen Biotech, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on August 24, 2018, I electronically filed the foregoing Answer using the CM/ECF system, which will send notification of such filing to all parties of record.

/s/ Leslie E. John